

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ )  
FENFLURAMINE/DEXFENFLURAMINE) ) MDL NO. 1203  
PRODUCTS LIABILITY LITIGATION )  
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THIS DOCUMENT RELATES TO: )  
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SHEILA BROWN, et al. ) CIVIL ACTION NO. 99-20593  
 )  
v. )  
 )  
AMERICAN HOME PRODUCTS ) 2:16 MD 1203  
CORPORATION )

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8975

Bartle, J.

November 17, 2012

Katie P. Graham ("Ms. Graham" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>3</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Preston L. Graham, Ms. Graham's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or  
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In December, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Dr. Evans is no stranger to this litigation. According to the Trust, he has signed at least 350 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated June 4, 2002, Dr. Evans attested in Part II of Ms. Graham's Green Form that she suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left

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3. (...continued)  
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

atrial dimension, and a reduced ejection fraction in the range of 50% to 60%. Based on such findings claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$486,424.<sup>4</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, R. Brian Fazia, M.D., F.A.C.C., stated that "[t]here is mild mitral insufficiency seen." Dr. Fazia, however, did not specify a percentage as to claimant's level of mitral regurgitation.<sup>5</sup> Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA").

See Settlement Agreement § I.22.

In January, 2006, the Trust forwarded the claim for review by Issam A. Mikati, M.D., one of its auditing cardiologists. In audit, Dr. Mikati concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because

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4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's findings of an abnormal left atrial dimension or a reduced ejection fraction, each of which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

5. Claimant also submitted an echocardiogram report prepared in October, 2002 by Dr. Evans based on her June 4, 2002 echocardiogram. In this report Dr. Evans stated, "There is moderate mitral regurgitation. The RJA/LAA ratio is 30%."

claimant's echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Mikati explained that the "[mitral regurgitation] is mild. Backflow must have been included to get ratio into moderate range."

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Graham's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contests this adverse determination.<sup>6</sup> In contest, claimant submitted affidavits from Dr. Evans and Don A. Francisco, M.D., F.A.C.C. In his affidavit, Dr. Evans confirmed his previous finding that claimant had moderate mitral regurgitation with an RJA/LAA ratio of 20% to 22%. Dr. Francisco also concluded that claimant's echocardiogram demonstrated moderate mitral regurgitation, and found "a RJA/LAA ratio of 29%." Claimant argued, therefore, that there was a reasonable medical basis for her claim because two Board-Certified Cardiologists agreed that she had moderate mitral regurgitation. Claimant further asserted that the auditing cardiologist "apparently did not understand the difference between his personal opinion ... and the 'reasonable medical basis'

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Graham's claim.

standard." (Emphasis in original.) In addition, claimant contended that, because the first auditing cardiologist who reviewed the echocardiogram of attestation found that there was a reasonable medical basis for the claim, there was sufficient evidence to support the attesting physician's finding of moderate mitral regurgitation.<sup>7</sup>

The Trust then issued a final post-audit determination, again denying Ms. Graham's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Graham's claim should be paid. On August 2, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6455 (Aug. 2, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 7, 2006, and claimant submitted a sur-reply on December 6, 2006. Under the

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7. In PTO No. 5632 (Aug. 26, 2005), we authorized the Trust to re-audit the claims of certain Diet Drug Recipients, including Ms. Graham, who opted out of the Seventh Amendment to the Settlement Agreement but did not elect to submit the initial audit of their claims to the Claims Integrity Process, based on the Trust's allegations that these initial audits were not reliable.

Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>8</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

to pay the claim in accordance with the Settlement Agreement.

See id. Rule 38(b).

In support of her claim, Ms. Graham repeats the arguments she made in contest; namely, that the opinions of Dr. Evans and Dr. Francisco, as well as the findings of the first auditing cardiologist, provide a reasonable medical basis for the finding of moderate mitral regurgitation. In addition, claimant contends that the concept of inter-reader variability accounts for the differences between the opinions provided by claimant's physicians and the auditing cardiologist, Dr. Mikati. According to claimant, there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, Ms. Graham contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that the RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA by an attesting physician is medically reasonable.

In response, the Trust argues that the opinions of claimant's physicians do not establish a reasonable medical basis for her claim because they never identified any high-velocity, sustained jets of mitral regurgitation seen in multiple consecutive frames. The Trust also notes that neither Dr. Evans nor Dr. Francisco addresses the original echocardiogram report prepared by Dr. Fazia, which indicates that claimant had only mild mitral regurgitation. In addition, the Trust asserts that the results of the initial audit of Ms. Graham's claim do not provide a reasonable medical basis for her claim because

Dr. Mikati, after receiving additional training, arrived at a different conclusion than the original auditing cardiologist. Finally, the Trust contends that inter-reader variability does not establish a reasonable medical basis for Ms. Graham's claim because Dr. Mikati specifically determined that there is no reasonable medical basis for the attesting physician's findings.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Abramson determined that:

In reviewing the transthoracic echocardiogram from 6/04/02, my visual estimate is that there is only mild mitral regurgitation in the parasternal views and the apical views. It is a very short echocardiogram with only one cardiac cycle obtained from each view. Therefore, there are only four views assessing mitral regurgitation- in the parasternal-long-axis, and three apical views. I measured the mitral regurgitant jet and the left atrial area (in the same frame) in each of the apical views (apical-4-chamber, apical-2-chamber, and apical-long-axis). My measurements for mitral regurgitant jet area/left atrial area are  $3.2\text{cm}^2/21.48\text{cm}^2$ ,  $3.7\text{cm}^2/24\text{cm}^2$ , and  $3.1\text{cm}^2/24.82\text{cm}^2$ . These ratios are 15%, 15%, and 12%, all of which are considerably less than 20%, and are consistent with mild mitral regurgitation. There are no measurements on the tape for me to critique.

After reviewing the entire Show Cause record, we find claimant's arguments are without merit. First, claimant does not refute the findings of the Technical Advisor. Claimant does not rebut Dr. Abramson's conclusion that "all of [the RJA/LAA ratios]

are considerably less than 20%, and are consistent with mild mitral regurgitation."<sup>9</sup> Although Ms. Graham submitted the opinions of two cardiologists, neither claimant nor her experts identified any particular error with the Technical Advisor. They also do not provide an explanation for the reviewing cardiologist's determination that claimant's echocardiogram demonstrated only mild mitral regurgitation. Mere disagreement with the Technical Advisor without identifying any specific errors is insufficient to meet a claimant's burden of proof.<sup>10</sup>

Moreover, we disagree with claimant that the opinions of her physicians establish a reasonable medical basis for her claim. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole;

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9. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

10. For this reason as well, the results of claimant's initial audit do not provide a reasonable medical basis for her attesting physician's representation that Ms. Graham suffered from moderate mitral regurgitation.

(4) over-manipulating the echocardiogram setting; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation.

See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here Dr. Mikati found, and claimant does not dispute, that Dr. Evans relied upon inaccurate measurements that included backflow, thus artificially overestimating claimant's level of mitral regurgitation.<sup>11</sup> Such an unacceptable practice cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

Finally, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Graham had moderate mitral regurgitation is misplaced. The concept of inter-reader variability already is encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the Technical Advisor concluded that all of the RJA/LAA ratios demonstrated on claimant's echocardiogram were no greater than 15%. Adopting

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11. For this reason as well, we reject claimant's argument that the auditing cardiologist simply substituted his personal opinion for the diagnosis of the attesting physician.

claimant's argument that inter-reader variability expands the range of moderate mitral regurgitation by  $\pm 15\%$  would allow a claimant to recover benefits with an RJA/LAA ratio as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.<sup>12</sup>

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Graham's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

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12. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in her statement that "it would be impossible for a reasonable echocardiographer to interpret this severity of mitral regurgitation as moderate even taking into account inter-reader variability."